UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION

CIVIL ACTION NUMBER:

1:19-md-02875-RBK-JS

ORAL OPINION DECIDING THE PARTIES' "MACRO" ISSUES LISTED IN THE OCTOBER 22, 2019 ORDER (DOCUMENT NO. 280)

Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101
Wednesday, November 20, 2019
Commencing at 2:12 p.m.

B E F O R E: **THE HONORABLE JOEL SCHNEIDER, UNITED STATES MAGISTRATE JUDGE**

A P P E A R A N C E S:

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQUIRE
103 Eisenhower Parkway
Roseland, New Jersey 07068
For the Plaintiff

LEVIN PAPANTONIO
BY: DANIEL A. NIGH, ESQUIRE
316 S. Baylen, Suite 600
Pennsacola, Florida 32502
For the Plaintiff

GOLOMB & HONIK PC
BY: RUBEN HONIK, ESQUIRE
DAVID JOHN STANOCH, ESQUIRE
1835 Market Street, Suite 2900
Philadelphia, Pennsylvania 19103
For the Plaintiff

Karen Friedlander, Official Court Reporter
friedlanderreporter@gmail.com
(856) 756-0160

Proceedings recorded by mechanical stenography; transcript produced by computer-aided transcription.

A P P E A R A N C E S: - CONTINUED

KANNER & WHITELEY LLC
BY: CONLEE S. WHITELEY, ESQUIRE
LAYNE CLARK HILTON, ESQUIRE
701 Camp Street
New Orleans, Louisiana 70130
For the Plaintiff

FARR LAW FIRM
BY: GEORGE T. WILLIAMSON, ESQUIRE
99 Nesbit Street
Punta Gorda, Florida 33950
For the Plaintiff

KIRTLAND & PACKARD LLP
BY: BEHRAM PAREKH, ESQUIRE
1638 South Pacific Coast Highway
Redondo Beach, California 90277
For the Plaintiff

GOLDENBERG LAW PLLC
BY: MARLENE J. GOLDENBERG, ESQUIRE
800 Lasalle Avenue
Suite 2150
Minneapolis, Minnesota 55402

DUANE MORRIS LLP
BY: SETH A. GOLDBERG, ESQ.
30 S. 17th Street
Philadelphia, Pennsylvania 19103
For the Defendant ZHP and the Joint Defense Group

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI LLP
BY: JASON M. REEFER, ESQUIRE
One Oxford Centre, 38th Floor
Pittsburgh, Pennsylvania 15219
For the Defendant Mylan and the Joint Defense Group

GREENBERG TRAURIG LLP
BY: BRIAN H. RUBENSTEIN, ESQUIRE
3333 Piedmont Road, NE, Suite 2500
Atlanta, Georgia 30305
For the Defendants, Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Actavis LLC, and Actavis Pharma, Inc.

THE DEPUTY CLERK: All rise.

(OPEN COURT; 2:12 p.m.)

THE COURT: Please be seated, counsel.

Okay. So, what the Court is going to do, it's going to read into the record its oral opinion ruling on all of the issues from today.

I'm going to confirm all of the rulings in an order which I hopefully will enter before the end of the week. In terms of the Court's oral opinion, the way it's organized is I'm just going to start out with some background and discuss some general issues, and then the meat of it is, obviously, the rulings on each specific issue.

So I thank the parties for their excellent briefs and argument. I hope I'm right that staging discovery this way helps advance the ball getting a decision, I hope, on the big-picture issues will help in your meet and confer sessions that are going to be ongoing in next few days. So here goes.

Presently before the Court to decide are what the Court has denominated macro discovery disputes. Although the term is not contained in the Federal Rules of Civil Procedure and is not normally part of a litigator's lexicon, the Court directed the parties to identify and brief important discovery disputes which are identified in the Court's October 21, 2019 order.

The term refers to big-picture discovery issues that

overarch the scope of relevant discovery. Experience has shown that the prompt identification and rulings on these disputes goes a long way towards effectively and efficiently managing the discovery process, especially in complex litigation like this MDL. The Court's rulings are a necessary precedent to deciding the more granular discovery disputes the Court will address and decide on December 11, 2019.

At the moment, the Court is just addressing discovery disputes between plaintiffs and the API and finished dose manufacturing defendants. The current API manufacturing defendants participating in the case are ZHP and Mylan. Aurobindo and Hetero have not yet been served pursuant to The Hague Convention, or if they have been served, they have not entered an appearance.

The finished dose manufacturers currently participating in the case, and I'm not providing the exact precise technical corporate name, are Aurolife or Aurobindo, Teva and Torrent.

The parties are obviously familiar with the background of this matter, so only a short summary will be provided.

This MDL arises out of contamination discovered in defendants' Valsartan medication in July 2018. Plaintiffs generally contend the contamination contained cancer-causing chemicals that has or will cause personal injuries, such as

cancer and liver damage, as well as economic losses. Defendants do not deny their Valsartan was contaminated but denied the contamination caused any injuries or damages.

The parties dispute important issues, such as the start date of the contamination, whether only the API was contaminated, the entire list of contaminating chemicals, and the facilities where the contamination occurred or should have been discovered.

The defendants in the case include manufacturers of the active pharmaceutical ingredient, or API manufacturers, finished dose manufacturers, wholesalers, distributors, repackagers and pharmacies. As noted, the discovery disputes to be addressed by the Court today only pertain to the API and finished dose manufacturers. Some of these parties are located in China and India. Macro and granular discovery disputes concerning the other categories of defendants will be addressed at a future date.

Plaintiffs' claims in the case have been grouped in the general categories that are reflected in the three filed master Complaints. The first master Complaint addresses the claims of individual plaintiffs who generally allege they contracted various forms of cancer from consuming defendants' contaminated Valsartan. To date, in excess of 125 personal injury cases of this type have been filed. Plaintiffs' counsel estimates approximately or perhaps 2,000 cases may

eventually be filed.

The second master Complaint is a nationwide medical monitoring class action filed on behalf of all "individuals who consumed contaminated generic Valsartan-containing drugs at least since January 1, 2012."

The potential class size is undoubtedly in the tens of thousands.

The third master Complaint is a nationwide economic class action filed on behalf of "all individuals and entities who since at least January 1, 2012, to the present, paid any amount of money for a Valsartan-containing drug."

Before it gets to the specific issues in dispute, the Court will address the general legal parameters that guide its rulings. The parties, of course, know the scope of relevant discovery is set forth in Rule 26(b)(1). Parties may obtain discovery of non-privileged information relevant to any party's claim or defense that is proportional to the needs of the case.

Although this MDL is or is likely to be massive in scope in terms of the number of potential claimants and the amount in controversy, the Court will not disregard the necessity of proportionality when it comes to deciding the discovery plaintiffs will be permitted to take.

The fact that this MDL is likely to involve thousands of potential claimants and disputes over hundreds of millions

of dollars is no reason to approve duplicative, unnecessary, cumulative, and unduly burdensome discovery.

On the other hand, when it evaluates the proportionality of plaintiffs' discovery requests, the Court cannot ignore the fact that hundreds of millions of dollars, perhaps even a billion dollars, may be in dispute.

The Court also cannot ignore the fact that Valsartan was and is a very popular high blood pressure medication perhaps taken by millions of people and that serious health concerns have been raised, although not yet proven, about the present and future health effects resulting from taking contaminated Valsartan.

It is beyond dispute that the public has a keen interest in the results of this litigation, and the issues in dispute are undoubtedly important to the public health and welfare. In addition, it is just as apparent that plaintiffs do not have access to the relevant information they need to prove their case, and that key information, such as when and how the Valsartan contamination occurred is within defendants' exclusive possession. These are relevant factors Rule 26 directs this Court to consider in its proportionality analysis.

The Court also wants to make a few general observations about the parties' discovery disputes so it does not have to repeat itself when it separately addresses each

dispute. As a general matter, the Court agrees that plaintiffs' discovery requests ask for relevant information. However, the Court would not be fulfilling its mission to secure the just, speedy, and inexpensive determination of this litigation if it gives plaintiffs everything they ask for.

A good example is plaintiffs' request for regulatory information from not only the FDA, but numerous other regulatory bodies around the world. It is hard to dispute that all work product related to the investigation of Valsartan contamination is relevant. Nevertheless, leaning on its experience and common sense, it is apparent that a lot of this discovery will be repetitive. The Court, therefore, must reasonably limit plaintiffs' discovery in order to prevent duplicative, cumulative, and minimally important discovery.

As to defendants, a common theme running throughout their briefs is that "the deal has already been sealed" on the cause of the Valsartan contamination, when it started, the chemicals at issue, the exposure levels that may be harmful, and when tests existed to identify the contaminants at issue. The Court does not agree.

Certainly, there are working theories regarding these issues, but by no means have the issues been finally resolved to everyone's satisfaction. In any event, plaintiffs are not bound to the prevailing theories and have the right to reach their own conclusions after obtaining relevant discovery from

defendants.

Importantly, the Court will not necessarily bind plaintiffs to the prevailing theories and assumptions made by the FDA, and as noted today, plaintiffs are not agreeing to be so bound. Plaintiffs have a right to reach their own conclusions. It is no secret, and today plaintiffs acknowledged, that as the case progresses, plaintiffs may question the FDA's competency, biases, and motivations.

Another general comment the Court makes relates to Judge Kugler's justifiable comment that discovery should focus on the crux of the merits. This Court obviously agrees. However, by no means did Judge Kugler intend to foreclose plaintiffs from obtaining otherwise relevant discovery that does not fit squarely into defendants' notion of a critical issue.

The Court does not intend to give plaintiffs free reign to discovery, but on the other hand, the Court will not tie plaintiffs' hands at this early stage of the case, which will prevent plaintiffs from investigating whether the current working theories of liability and causation are viable.

The Court adds the comment that it disagrees with and rejects any notion that the parties have not had sufficient time to meet and confer about the discovery issues in dispute. From the outset of the case, plaintiffs have urged defendants to meet in person to hammer out discovery issues, but

generally, plaintiffs faced resistance from defendants.

In fact, as a last resort, on November 7, 2019, the Court was compelled to order defendants to meet in person with plaintiffs. Further, plaintiffs' document request was served on August 31, 2019; therefore, defendants have had two months' notice of what plaintiffs requested.

In addition, the parties have been on notice of the specific macro issues in dispute no later than the Court's October 22, 2019 order. Therefore, the Court will not defer its decision on any relevant issue on account of the fact defendants want more time to meet and confer.

Last, the Court makes it clear that it is deciding the party's discovery disputes on the present record. If material new facts are raised that could not previously have been known, the parties may make a new application to the Court. Since most of the Court's rulings weigh discretionary factors, for the most part, the Court's rulings are without prejudice.

Moving on to the macro issues in dispute, the Court will first address the issues raised by plaintiffs and then proceed to defendants' issues. For the most part, the Court will give the parties general rulings on broad topics. The more granular issues will be addressed and decided on December 11, 2019, after the parties have had additional meet and confer sessions.

The first issue the Court will address is plaintiffs' request to strike all of defendants' boilerplate objections to their document requests. Plaintiffs referred to the objections filed by ZHP, Teva, Mylan, Aurobindo, and Torrent. Defendants argue the issue is moot because revised objections have been served, except for Mylan.

As a general matter, the Court agrees defendants initially served boilerplate objections. To say this is disappointing is an understatement. Given the caliber and experience of defense counsel and their law firms, one would think defendants would know better. This is especially true since the Court put defendants on notice of its disdain for boilerplate objections.

It is not hard for the Court to decide defendants' initial objections were improper. The harder question is what to do about it. The fact that except for Mylan, defendants served revised and updated objections is of no moment. The objections were served too late for plaintiffs to address them and for the Court to have a meaningful opportunity to rule on their merits.

While the Court would be fully justified in striking all of defendants' objections to plaintiffs' document requests, it will not do this. One, the Court's paramount concern is to make sure the case is decided on the merits, not procedural irregularities.

Two, the Court unfortunately recognizes it is not easy to change a defense culture that has built up over the years, but, however, this has to and will change.

Three, plaintiffs do not have complete clean hands. As defendants point out, the purpose of ordering core discovery was to get in plaintiffs' hands early in the case key information to enable plaintiffs to focus and narrow their discovery requests.

For the most part, plaintiffs did not do this, but instead served general and overbroad requests. While defendants' boilerplate objections were not appropriate, many of plaintiffs' document requests were facially inappropriate.

Rather than striking defendants' objections, the Court will leave defendants with a stern warning: In the future, the Court will not permit boilerplate objections and resistance to meaningful meet and confer sessions. Defendants are on notice that if this occurs in the future, their objections will be stricken and/or company representatives will be ordered to informally meet with plaintiffs. The Court is confident that in the future, only appropriate objections will be served and it will not see resistance to meaningful meet and confer sessions.

The second issue to be addressed by the Court is the manufacturing facilities that must respond to discovery.

Defendants want to limit discovery to only the API

facilities that made Valsartan that was recalled. In defendants' papers, they argue they also want to hold off on discovery regarding the finished dose manufacturing facilities until plaintiffs' document requests are served, albeit this position may have changed during oral argument.

Plaintiffs want discovery from every entity and manufacturing facility in the Valsartan distribution chain; in other words, as plaintiffs write, "Every facility with any role for Valsartan."

Starting with defendants' API manufacturing facilities, the Court rules that every facility that manufactured Valsartan API that was sold in the United States is a proper subject of discovery and not just those facilities that manufactured Valsartan that was recalled.

The reason is because it is not clear that only recalled Valsartan is at issue in the case. The recalled Valsartan presumably contained contaminants that were detected. Plaintiffs are arguing that the defendants' Valsartan may have been contaminated, even though there are no available, as of yet, confirmatory tests. At the end of the day, it may be clear when Valsartan contamination started and what facilities the Valsartan came from. This is not known at the moment. Discovery directed to all of defendants' manufacturing facilities that sold Valsartan in the United States is the only way for plaintiffs to learn the answers to

these key questions.

The Court adds that the specific documents each API manufacturing facility must produce remains to be decided, however, a good start is defendants' testing results, regulatory inspection reports and warning letters.

The Court also adds it does not expect the discovery to produced by the finished dose manufacturers to be as extensive as that produced by the API manufacturers.

As to the finished dose manufacturers, the Court rules that all of defendants' finished dose manufacturing facilities that made finished dose Valsartan that was sold in the United States is a proper subject of discovery.

Even if these facilities did not cause the contamination, a fact not yet confirmed, plaintiffs are arguing these facilities had an independent duty to investigate and discover the contamination. In this regard, plaintiffs need to find out if these facilities followed current good manufacturing procedures or practices. Plaintiffs are entitled to find out if these facilities had actual or constructive notice of the contaminated Valsartan API.

One plainly relevant topic of discovery is whether the finished dose manufacturers did or should have conducted tests to detect NDMA and NDEA. Plaintiffs argue defendants have a quality assurance obligation with regard to its API

suppliers' processes and finished product. Plaintiffs are entitled to discover what steps the finished dose manufacturers took in this regard and whether they knew or should have known about problems with their API suppliers' tests and processes.

For the same reasons, discovery directed to all of defendants' API manufacturing facilities that made Valsartan API sold in the United States are relevant for discovery purposes and not just the facilities that made the recalled lots. All of defendants' finished dose manufacturing facilities that sold product in the United States are relevant.

In order to foster productive meet and confer sessions, within one week and to the extent not already done, the Court orders the API and finished dose manufacturing defendants to identify each of their facilities that will be subject to discovery.

As to the specific documents the finished dose manufacturing facilities must produce, that will be decided by December 11, however, to be clear, the Court rules that defendants' finished dose manufacturing facilities that sold product in the United States are not off limits for discovery. At a minimum, these facilities must produce API testing results, inspection reports, and communications regarding potential or actual nitrosamine contamination. As to other

downstream facilities such as bottlers, repackagers, or labelers, these discovery issues will be addressed in January.

The third issue to be addressed is plaintiffs' request for discovery regarding other products using the same manufacturing processes, solvents and testing as those for Valsartan API. In other words, plaintiffs want discovery regarding other sartans, even though only Valsartan is currently at issue thus far in the case. For several reasons, plaintiffs' request for this discovery is denied, except for one caveat. First, even though other sartans may be similar to Valsartan, only Valsartan is at issue in the case at the present time. The discovery directed to Valsartan will undoubtedly be extensive. The Court is skeptical that any materially relevant information will be gleaned from non-Valsartan discovery that will not be learned from the Valsartan discovery.

Thus, the burden and expense of the non-Valsartan discovery is disproportional to its importance and relevance. The same is true for other processes using the same solvents at issue in this case.

Two, pending before the MDL panel is plaintiffs' application to expand the scope of this MDL to include other sartans. The panel should weigh in on the issue before the Court effectively makes other sartans part of the case.

Three, until the panel tells this Court otherwise,

the Court wants to keep the focus of the case on the penultimate Valsartan contamination issue. Discovery directed to other sartans' processes, testing and solvents will divert the parties' resources and attention away from the core issues in dispute.

As mentioned, there is one caveat to the Court's ruling cutting off plaintiffs' discovery directed to other sartans. Because of the importance of the issue and the closeness of the chemical structure of the different sartans, the Court will direct defendants to produce all documents reflecting the presence of any nitrosamine in any sartan product made prior to July 2018. This includes not only documents involving Valsartan, but other sartans, such as losartan, irbesartan, olmesartan and candesartan.

The fourth issue to be addressed is plaintiffs' requests for the dates, distribution lists, and preservation instructions in defendants' litigation hold letters for e-mails. Plaintiffs' request for this information is granted in part and denied in part. The Court relies on its discussion in *Major Tours*, 2009, Westlaw, 2413631, District of New Jersey, August 4, 2009, for the applicable law. There, the Court held that as a general matter, litigation hold letters are not discoverable unless there is a good faith basis to believe spoliation occurred.

The Court agrees now with what it said then. The

Court does not find that plaintiffs have as yet made a case that spoliation occurred in this case. The Court carefully reviewed plaintiffs' master Complaints and identified the instances where plaintiff cited to actual or potential destruction of documents. In those instances, however, they occurred long before July 2018 when defendants could reasonably foresee litigation.

Without the reasonable foreseeability of litigation, there was no duty to preserve documents under the common law and, therefore, no spoliation. Plaintiffs did not cite to or rely on any regulatory requirement to support their spoliation argument.

Despite the fact that defendants do not have to produce their hold letters or e-mails, they do have to identify all recipients of the hold letters or e-mails and when they were sent. As plaintiffs argue, these objective facts are relevant to the identification of knowledgeable witnesses and custodians and is not privileged or protected work product. To avoid any confusion or unnecessary disputes in the future, the Court wants to make one point clear, that is, that although defendants do not have to produce copies of their actual letters or e-mails, plaintiff may address preservation issues with defendants' deponents. Plaintiffs are entitled to know whether a witness received a hold request and what he or she did to preserve relevant information. This

topic is not privileged or work product and is not off limits at defendants' depositions. Last, the Court declines plaintiffs' request to review defendants' hold letters in camera.

Now that the Court has addressed the four issues raised in plaintiffs' opening brief, the Court will turn to the eight issues raised in defendants' opening brief. The first issue to be addressed is plaintiffs' request for foreign regulatory documents. Unfortunately, plaintiffs do not identify the specific regulatory bodies from whom they request documents, nor the specific documents they request.

Plaintiffs ask for all documents regarding the Valsartan recall, foreign inspection reports, foreign regulatory submissions and other similar documents. Defendants argue plaintiffs' discovery should be limited to the FDA.

As to regulatory documents in general, the Court has already ordered fulsome discovery of FDA documents. This was covered in the Court's core discovery order, an order requiring plaintiffs be sent copies of all ongoing relevant communications between the FDA and defendants. Thus, in the Court's belief, it is likely that all non-privileged relevant FDA information regarding the issues in this case has or will get into plaintiffs' hands.

The Court finds that plaintiffs have not shown that

carte blanche regulatory discovery is needed. No persuasive evidence has been presented that hoards of relevant information is in foreign regulatory hands but not in the possession of the FDA.

The Court believes that if it opens the door wide to foreign regulatory discovery, the parties will get bogged down in duplicative discovery.

The Court does not rule, however, that all foreign regulatory discovery is off limits. Plaintiffs are entitled to materially relevant discovery that is not likely already in FDA's possession.

The Court, therefore, will order defendants to produce for each of the relevant facilities in the case, regulatory inspection reports, warning letters akin to what the FDA sends, 483-like documents, defendants' responses to these documents, root cause analyses and communications regarding potential or actual nitrosamine contamination prior to July 28 that were sent to or received from any foreign regulatory body during the designated relevant time period.

The next issue defendants raise is plaintiffs' request for foreign sales marketing materials and agreements. This request is denied as the requested discovery is far afield from the material issues in the case.

The case involves sales of Valsartan in the United States and that is where the focus of plaintiffs' discovery

should and will be. Nonetheless, to the extent defendants have possession, custody, or control of documents from whatever source regarding unknown and unidentified testing peaks or general toxic impurities, the documents have to be produced. Plaintiffs' requests for all out-of-specification documents is too broad. This could involve issues such as the color, shape, texture, et cetera, of Valsartan, which is not relevant to the issues in the case.

Plaintiffs are directed to meet and confer with defendants on what they specifically want in this regard and raise disputes with the Court for the December 11th conference.

The next issue raised by defendants is the extent of discovery regarding each applicable defendants' finished dose manufacturing process. The Court has already discussed this issue and has nothing to add.

The fourth issue raised by defendants relates to what testing documents have to be produced. Although this is obviously one of the most important issues in the case, the plaintiffs are hamstrung in their discovery efforts, so they say, because they do not know the types of tests defendants conducted.

Clearly, plaintiffs are entitled to obtain discovery regarding any test that could identify the presence of nitrosamine contamination, such as NMBA and NDEA. The parties

apparently concede chromatography testing is relevant, but there may be other relevant tests. Defendants, therefore, and to the extent not already done, will be ordered to identify the types and purposes of the tests they ran at the subject facilities and to meet and confer with plaintiffs regarding the test results to be produced.

Disputes will be addressed on December 11. For the reasons already discussed, this ruling not only applies to API manufacturers but also to finished dose manufacturers. The parties should keep in mind that the facilities at issue are those that made products sold in the United States.

As to bioequivalence testing, this testing is relevant to the master economic loss claims and whether the purchasers got what they paid for. The testing is also relevant to whether defendants were or should have been aware of quality control issues, thus, bioequivalence testing shall be produced. Disputes regarding what testing should be produced, if any, should be raised in time to be addressed at the December 11 conference.

In order to avoid potential disputes, testing and results regarding other carcinogens, general toxic impurities or residual solvents in the Valsartan is relevant.

It would be anomalous to require defendants to produce test results revealing actual or potential NMBA or NDEA contamination, but not to reveal other similar toxic

contaminants. Albeit, one would think if this information existed, it would have already been turned over to the FDA.

The next issue to be addressed is the scope of health risk discovery. Defendants will be ordered to produce all documents, communications, and studies, et cetera, regarding the health effects of exposure to Valsartan contaminated with nitrosamines. Plaintiffs' request for health effect discovery regarding non-contaminated Valsartan is denied.

The next issue to be addressed is the relevant timeframe for general custodial searches. This is not an easy issue to decide, as both sides makes valid points. The Court ultimately concludes that it will not order the extensive time period plaintiff requests for general custodial searches. However, this does not foreclose plaintiffs from asking for earlier, discrete, and identifiable categories of documents or individual documents. To the extent plaintiffs and defendants cannot work out their issues, the Court will entertain the parties' discovery dispute and for good cause shown will order the production of earlier documents.

As to the relevant time period for general custodial searches, the Court will use the earliest date defendants proposed plus one year, starting from January 1. These dates are as follows: ZHP, January 1, 2010; Mylan, January 1, 2011; Teva, January 1, 2012; Torrent, January 1, 2013; Aurolife, January 1, 2012.

To repeat, the Court understands there are likely relevant older documents, but these will not be searched for until plaintiffs make a showing of good cause to produce discrete and identifiable documents or categories of documents.

As to Issues 7 and 8 in the Court's October 22nd, 2019 order, the parties have advised the Court that these issues are not in dispute, except the Court notes for the record a clarification that if a defendant has otherwise translated a document in the normal course of business and not just for litigation purposes, it will be produced by the defendants.

That completes the Court's oral opinion to be confirmed in an order to be entered. Counsel, if there are any other issues you want to address, I'll address them, but we can adjourn and head over to courtroom 4D to meet with Judge Kugler.

For the good of the order, plaintiffs, any other issues to address?

MR. SLATER: Nothing, Your Honor. We thank you for your hard work on this.

THE COURT: Thanks.

Defendants?

MR. GOLDBERG: Nothing, Your Honor. Thank you.

THE COURT: We're adjourned.

See you in courtroom 4D.

THE DEPUTY CLERK: All rise.

(2:55 p.m.)

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

/S/ Karen Friedlander, CRR, RMR
Court Reporter/Transcriber

11-21-19
Date